LEVERAGING DEVELOPMENT TO ADVANCE DIGITAL AND PAT TECHNOLOGIES IN MANUFACTURING

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Advancement of biomanufacturing process design and process analytical technologies (PAT) typically begins with process development. Years before a product moves to market, next generation processes are being developed to have greater efficiency and throughput. While developing next generation processes, successful process development organizations also invest in technologies to further improve biomanufacturing efficiency and robustness. Digital and PAT for process monitoring and control are no exception. The ability to mature technologies and move them to manufacturing is essential to remain competitive in today's industry climate. At Roche, we have embarked on a digital transformation in our development organization in order to accelerate pipeline development, deepen process understanding, and prepare for manufacturing processes of the future. Through this initiative, we are focused on increasing our data connectivity, predictive capabilities, and process monitoring sophistication. We expect this initiative to rapidly increase our rate of digital technology maturity and speed the development of digital technologies for biomanufacturing. With greater data connectivity, development will have access to broad data sets that allow for advanced learning, prediction, and modeling. The enhanced process understanding can then be transferred to manufacturing electronically and can be used to both generate instructions as well as build process models for monitoring and deviation resolution. Emerging from our digital transformation, Roche's process development organization will not only be able to deliver pipeline molecules more efficiently, we can do so with sophisticated process understanding enhanced by modeling and digital technologies to support PAT in biomanufacturing.